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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,987	02/04/2004	Pawan Seth	1259-001/CPB	3583

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EXAMINER	
PERREIRA, MELISSA JEAN	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
06/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/771,987	SETH ET AL.	
	Examiner	Art Unit	
	MELISSA PERREIRA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-31,33-59,61-85,87-109 and 114-120* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-31,33-59,61-85,87-109 and 114-120* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/25/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1,2,4-31,33-59,61-85,87-109 and 114-120 are pending in the application. Claims 3,32,60,86 and 110-113 were canceled in the amendment filed 4/25/08. Any objections and/or rejections from previous office actions that have not been reiterated in this office action are obviated.

1. The declaration under 37 CFR 1.132 filed 4/25/08 is insufficient to overcome the rejection of claims 1-4,6-14,16-22,28-32,34-42,44-50 and 56-58 based upon the rejection under 35 U.S.C. 102(e) as set forth in the last Office action because: the reference of Seth US 6,350,471 meets the limitation of the claims and the declaration cannot correct the inventorship of a US patent.

2. The declaration under 37 CFR 1.132 filed 4/25/08 is insufficient to overcome the rejection of claims 1-14,16-42,44-69,71-95 and 97-120 based upon the rejection under 35 U.S.C. 103(a) as being unpatentable over Seth (US 6,350,471B1) in view of Buhler et al. (US 6,592,900B1) and/or Remington's Pharmaceutical Sciences **1990** 18th Ed. Chpt. 89, p1637 as set forth in the last office action because: the declaration does not state that the invention was commonly owned at the invention was made.

Response to Arguments

1. Applicant's arguments filed 4/25/08 have been fully considered but they are not persuasive.

2. Claims 1,2,4,6-14,16-22,28-31,34-42,44-50 and 56-58 are rejected under 35 U.S.C. 102(e) as being anticipated by Seth (US 6,350471B1) as stated in the office action mailed 10/26/07.

3. Applicant asserts that Seth does not teach or suggest a core containing metformin but that a mere reference stating, "the cores are coated with a coating designed to achieve a controlled release of metformin", is not by itself a teaching that the cores contain metformin.

4. Seth explicitly states, "the tablet cores are then coated with the semi-permeable coating designed to achieve a controlled release of metformin" (column 2, lines 26-28). It is anticipated by this statement that cores of the disclosure contain metformin.

5. Claims 1,2,4-14,16-31,33-42,44-59,61-69,71-85,87-95,97-109 and 114-120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seth (US 6,350,471B1) in view of Buhler et al. (US 6,592,900B1) and/or Remington's Pharmaceutical Sciences **1990** 18th Ed. Chpt. 89, p1637 as stated in the office action mailed 10/26/07.

6. Applicant asserts that Seth does not teach or suggest a core containing metformin but that a mere reference stating, "the cores are coated with a coating designed to achieve a controlled release of metformin", is not by itself a teaching that the cores contain metformin.

7. Seth explicitly states, "the tablet cores are then coated with the semi-permeable coating designed to achieve a controlled release of metformin" (column 2, lines 26-28). It is anticipated by this statement that cores of the disclosure contain metformin.

8. At the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize use polyvinylpyrrolidone or its equivalent, crospovidone, as a disintegrant/expanding agent for a tablet preparation (Buhler et al). Also sodium starch glycolate is a well-known and commonly used disintegrants/expanding agent for tablet preparations (Remington's). One would have a reasonable expectation of success for substituting the polyvinylpyrrolidone contained in the core of the extended release tablet of Seth for the crospovidone or sodium starch glycolate.

New Grounds of Rejection Necessitated by the Amendment

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1,2,4-31,33-59,61-85,87-109 and 114-120 rejected under 35 U.S.C. 103(a) as being unpatentable over Seth (US 6,350,471B1) in view of Moeckel et al. (US 5,955,106) and in further view of Buhler et al. (US 6,592,900B1) and/or Remington's Pharmaceutical Sciences **1990** 18th Ed. Chpt. 89, p1637.

11. Seth (US 6,350471B1) discloses an extended release pharmaceutical tablet that contains a core comprising metformin (column 2, lines 26-28), a lubricant (i.e. stearic acid, glyceryl behenate) (column 1, lines 39-40), a water-soluble binder (i.e. polyvinylalcohol) (column 1, line 44), silicone dioxide (column 3, lines 26-30) and a

coating, free of monomeric pore-forming agent, comprising a water-insoluble, water-permeable film-forming polymer (i.e. ethyl cellulose) (column 2, line 35), water-soluble polymer (i.e. polyvinylpyrrolidone, hydroxypropylcellulose) (column 2, lines 41-42) and a plasticizer (i.e. stearic acid, dibutyl sebacate) (column 2, lines 36-40 and 61-63; column 3, lines 31-34). The proportion of water-insoluble polymer, water-permeable film-forming polymer is between 20-85%, the proportion of water-soluble polymer is 10-75% and the proportion of plasticizer is 5-30% (column 2, lines 47-54). The dissolution profile of the tablets free of monomeric pore-forming agent is that after 2 hours from 5-40% of metformin is released, after 4 hours 10-60% is released, after 12 hours 50-98% is released and after 24 hours more than 80% is released (column 3, lines 15-21). Seth does not disclose the water-soluble polymer, hydroxypropylmethylcellulose. Also, Seth does not disclose crospovidone or starch glycolate as a disintegrant.

12. Moeckel et al. (US 5,955,106) discloses an extended release pharmaceutical tablet that contains metformin hydrochloride in about 70-95% (i.e. 850 mg) (column 1, lines 8-13; column 2, lines 23-24), hydrophilic swelling/expanding substances (i.e. polyvinyl alcohol or polyvinylpyrrolidone, hydroxypropyl methylcellulose, etc.) (column 1, lines 20-30), a film former (i.e. ethyl cellulose, methylhydroxypropyl cellulose) (column 1, lines 55-57 and 67; column 2, lines 5-6; column 4, line 2), silicon dioxide and stearic acid (column 2, line 35). The core of the tablet contains the metformin, the expanding substance and magnesium stearate (stearic acid) which is coated with ethyl cellulose via the standard coating process (column 5, lines 13-14; example 1). The controlled release of metformin from the tablets of the disclosure should be over a time period of

0.5-10 hours (column 5, lines 31-33). The extended release pharmaceutical tablet of the disclosure encompasses the extended release pharmaceutical tablet of the instant claims and should therefore be capable of the same functions and have the same properties, such as the dissolution profile.

13. Buhler et al. (US 6,592,900B1) discloses the use of crospovidone/polyvinylpyrrolidone as a disintegrant for tablets whereas crospovione is particularly suitable disintegrant (column 3, lines 24-26; column 2, lines 42-43).

14. Remington's Pharmaceutical Sciences **1990** 18th Ed. Chpt. 89, p1637 discloses crospovidone and sodium starch glycolate as well known and commonly used disintegrants/expanding agents for tablet preparations. Sodium starch glycolate is known to swell seven- to twelvefold in all three dimensions in less than 30 sec. The disintegrating agent is mixed with the active agent and diluents prior to granulation (p37, paragraph 7,8 and 10).

15. The extended release pharmaceutical tablet of the combined disclosures encompass the extended release pharmaceutical tablet of the instant claims and should therefore be capable of the same functions and have the same properties, such as the dissolution profile. Furthermore, it is obvious to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance provided by (reference), to provide a composition having the desired properties such as the desired (ratios, concentrations, percentages, etc.). It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the

optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

16. At the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize polyvinylpyrrolidone or its equivalent, crospovidone, as a disintegrant/expanding agent for a tablet preparation (Buhler et al). Also sodium starch glycolate is a well known and commonly used disintegrants/expanding agent for tablet preparations (Remington's). One would have a reasonable expectation of success for substituting the polyvinylpyrrolidone contained in the core of the extended release tablet of Moeckel et al. for the crospovidone or sodium starch glycolate. Also, Moeckel et al. discloses the use of polyvinyl alcohol or polyvinylpyrrolidone and hydroxypropyl methylcellulose interchangeably for the extended release pharmaceutical tablets of the disclosure and therefore it would be obvious to substitute the polyvinylpyrrolidone of the extended release pharmaceutical tablet of Seth for the hydroxypropyl methylcellulose of the extended release pharmaceutical tablet of Moeckel et al.

17. Claims 1,2,4-31,33-59,61-85,87-109 and 114-120 rejected under 35 U.S.C. 103(a) as being unpatentable over Seth (US 6,350,471B1) in view of Cheng et al. (US 6,099,859) and further in view of Buhler et al. (US 6,592,900B1) and/or Remington's Pharmaceutical Sciences **1990** 18th Ed. Chpt. 89, p1637.

18. Seth (US 6,350471B1) discloses an extended release pharmaceutical tablet that contains a core comprising metformin (column 2, lines 26-28), a lubricant (i.e. stearic acid, glyceryl behenate) (column 1, lines 39-40), a water-soluble binder (i.e.

polyvinylalcohol) (column 1, line 44), silicone dioxide (column 3, lines 26-30) and a coating, free of monomeric pore-forming agent, comprising a water-insoluble, water-permeable film-forming polymer (i.e. ethyl cellulose) (column 2, line 35), water-soluble polymer (i.e. polyvinylpyrrolidone, hydroxypropylcellulose) (column 2, lines 41-42) and a plasticizer (i.e. stearic acid, dibutyl sebacate) as well as that stated above. Seth does not disclose the water-soluble polymer, hydroxypropylmethylcellulose. Also, Seth does not disclose crospovidone or starch glycolate as a disintegrant.

19. Cheng et al. (US 6,099,859) discloses an extended release pharmaceutical tablet that contains a core of metformin hydrochloride in about 50-98% or 75-95% (850 mg) (column 3, lines 39 and 66+; column 5, lines 35-41; example 3), a binder (i.e. polyvinylpyrrolidone) in about 0-40% (column 3, lines 40-41 and 48) coated by a semipermeable membrane in about 50-99% (column 4, lines 11,29 and 58). The semipermeable membrane may consist of polymer(s) (i.e. cellulose ethers, hydroxypropyl methylcellulose, polyvinyl alcohol, cellulose acetate, hydroxypropyl cellulose) and a plasticizer (i.e. stearate or dibutylsebacate in about 0-25% (column 4, lines 40 and 61; column 5, line 3; column 6, line 56). The dissolution of the tablet provides for treatment over a twelve to twenty-four hour period (column 2, lines 16-21; column 5, lines 51-57; column 7, lines 13-18).

20. Buhler et al. (US 6,592,900B1) discloses the use of crospovidone/polyvinylpyrrolidone as a disintegrant for tablets whereas crospovione is particularly suitable disintegrant (column 3, lines 24-26; column 2, lines 42-43).

21. Remington's Pharmaceutical Sciences **1990** 18th Ed. Chpt. 89, p1637 discloses crospovidone and sodium starch glycolate as well known and commonly used disintegrants/expanding agents for tablet preparations. Sodium starch glycolate is known to swell seven- to twelvefold in all three dimensions in less than 30 sec. The disintegrating agent is mixed with the active agent and diluents prior to granulation (p37, paragraph 7,8 and 10).

22. The extended release pharmaceutical tablet of the disclosure encompasses the extended release pharmaceutical tablet of the instant claims and should therefore be capable of the same functions and have the same properties, such as the dissolution profile. Furthermore, it is obvious to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance provided by (reference), to provide a composition having the desired properties such as the desired (ratios, concentrations, percentages, etc.). It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

23. At the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize use polyvinylpyrrolidone or its equivalent, crospovidone, as a disintegrant/expanding agent for a tablet preparation (Buhler et al). Also, sodium starch glycolate is a well known and commonly used disintegrants/expanding agent for tablet preparations (Remington's). One would have a reasonable expectation of success for substituting the polyvinylpyrrolidone contained in the core of the extended release tablet

of Cheng et al. for the crospovidone or sodium starch glycolate. Also, Cheng et al. discloses the use of semipermeable membrane polymer(s), i.e. cellulose ethers, polyvinyl alcohol, cellulose acetate,hydroxypropyl cellulose and hydroxypropyl methylcellulose interchangeably for the extended release pharmaceutical tablets of the disclosure and therefore it would be obvious to substitute the hydroxypropyl cellulose of the extended release pharmaceutical tablet of Seth for the hydroxypropyl methylcellulose of the extended release pharmaceutical tablet of Cheng et al.

Conclusion

No claims are allowed at this time.

24. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/
Examiner, Art Unit 1618